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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,844	06/23/2003	Manne Satyanarayana Reddy	BULK 3.0-018	9550

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EXAMINER

WARD, PAUL V

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,844	Applicant(s) REDDY ET AL.	
	Examiner PAUL V. WARD	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
 4a) Of the above claim(s) 19-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on February 21, 2006 is acknowledged. The traversal is on the ground(s) that the claims of the instant application relate to a single compound and the processes for preparing a different compound will not be relevant to determining patentability of the claims for preparing amorphous levocetirizine dihydrochloride, and thus, there can be no undue burden placed on the Examiner. This is not found persuasive because the process as claimed can be used to make other and materially different products, such as levocetirizine dihydrochlorides. Thus, the inventions of Groups I and II are separate and patentably distinct because there is no patentable co-action among them and a reference anticipating one member will not render another obvious.

The requirement is still deemed proper and is therefore made **FINAL**.

Applicant is reminded that if the claims of Group I are allowed, then the claims of Group II will automatically be rejoined.

Group II is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

An action on the merits of Group I (claims 1-18) is contained herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim refers to a Figure. Correction is required.
2. The term "substantially" in claims 2 and 10 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al. (J'China Pharm Univ).

Applicant claims amorphous levocetirizine dihydrochloride, amorphous levocetirizine dihydrochloride free of crystalline forms of cetirizine dihydrochloride, and compositions comprising the levocetirizine dihydrochloride. Additionally, Applicant claims compositions of levocetirizine dihydrochloride containing a moisture content ranging from about 0.3 % to 12% using the KF method.

Tang teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 311, Fig. 1 pg. 311, and

Figures 2-3 on pg. 312). Since Tang teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Pflum (Organic Process Research & Development' 2001).

Pflum teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 110, Fig. 1 pg. 110, and Tables 2-3 on pg. 111 and left col.). Additionally, on page 111, left hand column, and on page 112, right hand column (last paragraph), Pflum teaches that the levocetirizine contain yields of 79% and 99%. Since Pflum teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

5. Claims 4-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Van de Venne et al. (U.S. Patent 6489329).

Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, and falls within the range of Applicant's compounds. (See Abstract, col. 3 lines 45-60, col. 5, lines 10-55, and Table in col. 6). Since Van de Venne teaches the exact compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van de Venne et al. (U.S. Patent 6489329).

Applicant claims compositions comprising levocetirizine dihydrochloride containing a moisture content ranging from about 0.3 % to 12% using the KF method.

Van de Venne teaches compositions comprising levocetirizine dihydrochloride (See Abstract and columns 3-6). The claims differ from the reference by reciting the composition containing a moisture content.

Thus, Van de Venne does not teach Applicant claims in the same format as claimed by applicant, however, one skilled in the art would find the differences in the teaching to be negligible. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Van de Venne to obtain the compositions as claimed in the instant application. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for levocetirizine compositions. See *In re Payne*, 203 USPQ 245 (CCPA 1979). Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Conclusion

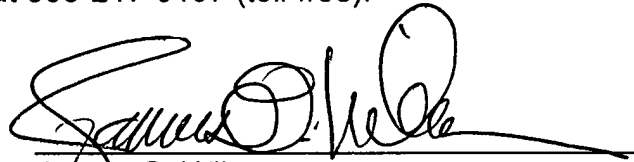
Claims 1-18 are pending. Claims 1-18 are rejected. No claims are allowed.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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